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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/762,763

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EXAMINER

AGRAWAL, RITESH

ART UNIT

PAPER NUMBER

1631

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/762,763	Applicant(s) VOCKLEY ET AL.	
	Examiner Ritesh Agrawal	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2006 and 14 December 2006 and.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' amendment filed on 10/12/06, 12/14/06, and 3/08/07 are acknowledged and entered.

Claims 5-13 are currently pending and under consideration.

Withdrawn Rejections

2. The prior rejection of claims 1-4 under 35 U.S.C. 102 (b) over Khan et al. and the 102 (a,e) art rejection over Person et al. are withdrawn in light of applicants' cancellation of these claims.

The rejection of claim 7 under 35 U.S.C. 112, second paragraph, an indefiniteness rejection, is hereby withdrawn in light of the amendments to the claims filed 10/12/06.

The rejection of claims 12-13 under 35 U.S.C. 112, second paragraph for omitting essential steps, is hereby withdrawn in light of the amendments to the claims filed 10/12/06.

Specification

3. The specification is objected to because of the following:

The information relating to the government contract number on page 1 of the specification is left blank.

The above objections have been reiterated from the previous Office action.

Applicant's arguments have been fully considered but they are not persuasive.

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With respect to the government contract number, applicant argues "that a reference will be added to the application promptly upon identification." Until such time as a reference is added, the objection shall be maintained.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 5-13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. This rejection is newly applied.

Claims 5-7 and 12 are drawn to a process. A statutory process must include a step of a physical transformation, or produce a useful, concrete, and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)). The instant claims do not result in a physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

As noted in State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998) below, the statutory category of the claimed subject matter is not relevant to a determination of whether the claimed subject matter produces a useful, concrete, and tangible result:

The question of whether a claim encompasses statutory subject matter should not focus on *which* of the four categories of subject matter a claim is directed to 9-- process, machine, manufacture,

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or composition of matter--but rather on the essential characteristics of the subject matter, in particular, its practical utility. Section 101 specifies that statutory subject matter must also satisfy the other "conditions and requirements" of Title 35, including novelty, nonobviousness, and adequacy of disclosure and notice. See *In re Warmerdam* , 33 F.3d 1354, 1359, 31 USPQ2d 1754, 1757-58 (Fed. Cir. 1994). For purpose of our analysis, as noted above, claim 1 is directed to a machine programmed with the Hub and Spoke software and admittedly produces a "useful, concrete, and tangible result." *Alappat* , 33 F.3d at 1544, 31 USPQ2d at 1557. This renders it statutory subject matter, even if the useful result is expressed in numbers, such as price, profit, percentage, cost, or loss.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be "tangible," the process must produce a real world result . Furthermore, the claim must be limited only to statutory embodiments.

Claims 5-13 do not produce a tangible result. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display or a memory or another computer on a network, or to a user, or by including a physical transformation.

With respect to claims 8-11 and 13, the placement of a non-statutory process on a computer readable medium does not make it statutory. As cited above, whether a claimed invention is statutory is based upon its essential characteristics, not which of the four categories to which it belongs. As the essential characteristics of the inventions

encompassed by the computer readable medium claims are the method, and the method is non-statutory, so are the claims to the computer-readable medium.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 7 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is newly applied, but necessitated by amendment.

Claim 7 recites the limitation "the first and second selected databases is GENBANK genomic data source" in lines 2-3. It is unclear if the first and second databases comprise the entirety of the GENBANK database, or that they only use GENBANK as a genomic data source and therefore may comprise any subset of the GENBANK database.

Claim 12 recites the limitation "searching a selected genomic database" in line 7. It is unclear whether the selected genomic database includes or excludes sequences from the set of organisms under investigation.

Claim 12 recites the limitation "the query" in line 7. There is insufficient antecedent basis for this limitation in the claim. There is no prior reference to a "query" in the claim. It is unclear if a "query" is the same as a "query-length sequence".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 5, and 8-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Xu et al. (Bioinformatics, vol. 18, pages 1432-1437, November 1st, 2002).

The claims are drawn to a method and program for identifying unique oligonucleotide sequences.

Xu et al. disclose a method for identifying unique (termed specific) oligonucleotides and provide a computer program termed PRIMEGENES for carrying out the method. They disclose obtaining data for two bacterial species, "an application of the program using ORFs from *Shewanella onidensis* MR-1 and *Deinococcus radiodurans* R1 are presented," (page 1433, 1st column, 1st paragraph, lines 7-10). They search query sequences with a first homology search engine," PRIMEGENES first carries out the heuristic BLAST search for each ORF (query) against all other ORFs to quickly identify possible homologous sequences," (page 1433, 1st column, 2nd paragraph, lines 4-7). They divide these original queries into smaller fragments for use in primer design," PRIMEGENES selects the gene-specific fragments . . .

PRIMEGENES uses a third-party software, Primer3, which takes a DNA fragment

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selected in the first task and designs PCR primer pairs," (page 1433, 1st column, 2nd paragraph, lines 10-11; 14-17). Furthermore, they carry out a second homology search with their target oligonucleotide sequences, "to further ensure that the primer will not amplify multiple sequences, gapless sequence alignments are carried out between the two primers and all the ORFs, " (page 1433, 1st column, 2nd paragraph, lines 19-22).

While not explicitly stated, as the PRIMEGENES program represents an automatic method, the methodology of PRIMEGENES must inherently format and parse data in order to carry out the homology searches and to identify homologous sequences from the searching steps.

In the absence of an explicit definition for the term combine, the term will be defined as "to possess or exhibit in combination," (dictionary.com, 2006). As such, when applied to limitations disclosed above, the PRIMEGENES program of Xu et al. discloses the limitations of claims 9-11, that is, it combines a first and second search module, a first and second parsing module, and a first and second formatting module.

The above rejections have been reiterated from the previous Office action.

Applicant's arguments have been fully considered, but they are not persuasive.

Applicant argues that:

Mere alignment can be one aspect of a similarity search engine, both the present application and Xu distinguish between a similarity search engine (such as BLAST) and mere alignment. Xu's "alignment" does not disclose searching a second genomic database using a similarity search engine (remarks, page 13, 1st paragraph).

Applicant, exemplifies, but does not define either the term "similarity search engine" or "genomic database." While Xu does separate a BLAST search from carrying out alignment, Xu only suggests they are different with respect to speed and optimality.

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Xu does not suggest that they are different because one represents a “similarity search engine” and the other does not. In the absence of explicit definitions for the term “similarity search engine” a broadest reasonable interpretation includes any method used to determine the similarity amongst a set of sequences that includes the sequence alignment method of Xu et al. Despite applicant’s assertion that Xu et al. “mere[ly]” carry out an alignment, it is clear that they carry out an alignment to determine the similarity of selected oligonucleotide sequences with other genomic regions (see the cited text from Xu et al. page 1433, lines 19-22, above). As argued in the obviousness rejection (below), given that Xu et al. specifically point out that the “alignment” can be replaced by a BLAST search (where applicants’ define a BLAST search as a search engine), one would reasonably interpret that alignment is functionally equivalent to a BLAST search and therefore functionally equivalent to using a search engine. Furthermore, in the absence of an explicit definition for the term “genomic database” a broadest reasonable interpretation includes any set of genomic sequences. As Xu is carrying out sequence alignments against a set of genomic sequences, Xu’s set of genomic sequences reasonably represents a “genomic database.”

7. Claims 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Lai et al. (*Biochimica et Biophysica Acta*, Vol. 1517, Pages 449-454, 2001). This rejection is newly applied.

Claim 12 is drawn to a method comprising:

obtaining genomic data from a first set of organisms,

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formatting the genomic data into query-length sequences,
searching a genomic database using the query-length sequences,
parsing the results of the search for sequences having homology above a
threshold where the sequences come from an organism other than the organism
from which the query sequence was derived.

Lai et al. disclose a method for obtaining EST sequences from humans (page 449, 2nd column, lines 2-4). They format these sequences to be used by a BLAST search engine (page 449, 2nd column, lines 5-6). They search a database of *Drosophila* sequences (page 449, 2nd column, line 11) and parse the results (page 449, 2nd column, lines 12-13) to identify *Drosophila* sequences having homology above a given threshold (page 449, 2nd column, lines 7-8).

With respect to claim 13, it represents a computer program product for carrying out the method of claim 12. As Lai et al. disclose a computer program product for carrying out their method (page 449, 2nd column, lines 9-10), their computer program product anticipates the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8: Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al. as applied to claims 5, 8, and 9-11 above.

The claim is drawn to a method for identifying unique oligonucleotide sequences where a first and second similarity search engine is BLAST.

Xu et al. disclose a method for identifying unique oligonucleotide sequences using two search engines where the first is a BLAST search but Xu et al. do not disclose using a BLAST search for their second search engine.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the second search engine of Xu et al such that it was a BLAST search engine. One having ordinary skill in the art would have been motivated to use the BLAST search engine since Xu et al. clearly disclose that, "dynamic programming is slower than BLAST," (page 1433, 2nd column, 2nd paragraph, lines 7-8). Thus, by using the BLAST search engine, one could obtain the relevant data more expediently than by using dynamic programming.

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The above rejection has been reiterated from the previous Office action.

Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues:

Claim 6, as dependent on Claim 5, requires two searches against a genomic database(s) using a similarity search engine(s). Claim 6 further specifies BLAST as the similarity search engine (remarks, page 13, 2nd paragraph).

The OA implies that Xu's mere alignment is a similarity search engine. As noted above with respect to Claims 5 and 8-11, this is not the case (remarks, page 13, 3rd paragraph).

As argued above, Xu's alignment reasonably represents a "similarity search engine" and Xu's collection of genomic sequences to which putative oligonucleotides are aligned reasonably represents a "genomic database." Therefore, Xu's method provides for two searches using two search engines against genomic databases. Given the rationale provided above, it would have been obvious to modify Xu's second search engine to be a BLAST search engine therefore meeting the limitations of claim 6.

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al. as applied to claims 5, 8, and 9-11 above, and further in view of Benson et al. (Nucleic Acids Research, Vol. 21, Pages 2963-2965, 1993). This rejection is newly applied.

The claim is drawn to the method of claim 5 with the additional limitation that both the first and second databases be GENBANK.

Xu et al. disclose the method of claim 5 (as discussed under the 102(a) rejection), but do not disclose using GENBANK as their first and second databases.

Benson et al. disclose the GENBANK database (see, for example, abstract).

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It would have been obvious, for one of ordinary skill in the art, at the time the invention was made, to modify the method of Xu to use the GENBANK database of Benson. One of ordinary skill in the art would have been motivated to do so because, as taught by Benson, the GENBANK database had all known sequences (page 2963, 1st column, 1st paragraph, lines 1-3) whereas the databases used by Xu only has a small subset thereof. The use of a database with a greater number of sequences would further prevent identifying probes that may cross-hybridize; a problem which Xu et al. highlight as being an important consideration in probe design (for example, page 1432, 2nd column, lines 3-5).

Conclusion

10. No claim is allowed.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ritesh Agrawal whose telephone number is (571) 272-2906. The examiner can normally be reached on 8:30 AM - 5:00 PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ritesh Agrawal RA

John S. Brusca
22 May 2007

JOHN S. BRUSCA, PH.D.
PRIMARY EXAMINER